

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Efficacy of Photodynamic therapy with topical Indocyanine green in the treatment of Keloidal lesions

#### Protocol summary

##### Study aim

Efficacy of Photodynamic therapy with topical indocyanine green in the treatment of Keloidal lesions

##### Design

clinical trial, pilot study

##### Settings and conduct

before the therapeutic sessions, small amount of ICG ointment applied in lateral side of arm and the patient being informed not to touch or rinse the place. after 48 hours we look the place for any kind of skin reactions and if there was no skin reactions the patient is allowed to enter to trial. first a basic photograph of the lesion being taken and the dimensions are determined. lesions being covered with ICG ointment with 1mm thickness on top and 5mm around and its covered with biofilm for 1 hour. then the lesions being wiped off and it goes under photodynamic therapy with source LumaCare with 730 nm probe every 2 weeks and total of 6 sessions. patients being assessed in 6 and 12 weeks after the treatment sessions for any recurrences. the place we do the trial is in dermatology outpatient clinic of imam Reza hospital in Mashhad

##### Participants/Inclusion and exclusion criteria

The patients with minimum age of 18 years old are being selected based on dermatologist diagnosis as having idiopathic keloids. They have no history of any medical treatments for their lesions in 3 last months. only lesions that are located on trunk, extremities, back and buttock are being selected.

##### Intervention groups

patients who undergo using indocyanine green ointment and photodynamic therapy

##### Main outcome variables

determining efficacy of Photodynamic therapy with topical indocyanine green in the treatment of Keloidal lesions

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201221049780N1**

Registration date: **2021-03-17, 1399/12/27**

Registration timing: **prospective**

Last update: **2021-03-17, 1399/12/27**

Update count: **0**

##### Registration date

2021-03-17, 1399/12/27

##### Registrant information

##### Name

Sara Fakhraei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3876 0858

##### Email address

sarai.fakhraei@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-21, 1400/02/01

##### Expected recruitment end date

2021-10-23, 1400/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of Photodynamic therapy with topical Indocyanine green in the treatment of Keloidal lesions

#### Public title

Efficacy of Photodynamic therapy with topical Indocyanine green in the treatment of Keloidal lesions

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

the patients are selected based on dermatologist diagnosis as having idiopathic keloids minimum age for being selected is 18 years old patients have no history of any medical treatments for their lesions at least in 3 months lesions are on trunk, extremities, back and buttock

##### Exclusion criteria:

any skin disease or abnormality around the lesion for example dermatitis, bacterial or fungal infections pregnancy lactation lesions on face and genitalia history of any medical treatments for their lesions in 3 last months

#### Age

From **18 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **15**

More than 1 sample in each individual

Number of samples in each individual: **2**

2 keloidal lesions of any patients are being selected

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Single

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

###### Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9177899191

#### Approval date

2020-12-21, 1399/10/01

#### Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.542

### Health conditions studied

#### 1

##### Description of health condition studied

keloid

##### ICD-10 code

L91.0

##### ICD-10 code description

Hypertrophic scar

### Primary outcomes

#### 1

##### Description

improvement of keloidal lesions based on POSAS score

##### Timepoint

before the trial, every month after starting trial, in 6th and 12th weeks after finishing the trial

##### Method of measurement

Patient and Observer Scar Assessment Scale

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: patients under treatment with indocyanine green 0.2% ointment and photodynamic therapy after 1 hour, every 2 weeks for total of 6 sessions

##### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Dermatology Clinic of Imam Reza Hospital of Mashhad City

###### Full name of responsible person

Ahmad Reza Taheri

###### Street address

Imam Reza Hospital, Imam Reza square, Ebn\_e\_sina Avenue  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Dr Mohsen Tafaghodi  
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Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street  
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ramresearch@mums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Mashhad University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**

Sara Fakhraei  
**Position**  
dermatology resident  
**Latest degree**  
Medical doctor  
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Dermatology  
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## Person responsible for scientific inquiries

#### Contact

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Ahmadreza Taheri Bojd  
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Associate professor  
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Specialist  
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## Person responsible for updating data

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Medical doctor  
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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to

make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available